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10/619,766	07/15/2003	Christopher Charles Abney	PR60153US1	8793

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GLAXOSMITHKLINE
CORPORATE INTELLECTUAL PROPERTY, MAI B475
FIVE MOORE DR., PO BOX 13398
RESEARCH TRIANGLE PARK, NC 27709-3398

EXAMINER	
STITZEL, DAVID PAUL	

ART UNIT	PAPER NUMBER
1616	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/619,766	ABNEY ET AL.	
	Examiner	Art Unit	
	David P. Stitzel, Esq.	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 March 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8,11-18 and 61-63* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8,11-18 and 61-63* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

OFFICIAL ACTION

Acknowledgment of Receipt

Receipt of the Applicants' Response and Amendment, which was filed on March 24, 2006, in response to the Official Action dated December 27, 2005, is acknowledged.

Status of Claims

Claims 1 and 17 have been amended, claims 9, 10 and 19-60 have been cancelled, and claims 61-63 have been added by the aforementioned Amendment. As a result, claims 1-8, 11-18 and 61-63 are currently pending and therefore examined herein on the merits for patentability.

Claim Rejections - 35 U.S.C. § 102

The following is a quotation of the appropriate paragraph of 35 U.S.C. § 102, which forms the basis of the anticipation rejections as set forth under this particular section of the Official Action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1-5 and 61 are rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent 6,365,196 (hereinafter the Venkatesh '196 patent).

With respect to claims 1-5 and 61 of the instant application, the Venkatesh '196 patent discloses a controlled release pharmaceutical composition in solid dosage form for oral administration in the treatment of manic depression, wherein said pharmaceutical composition comprises: lithium carbonate present in an amount from about 40 wt. % to about 90 wt. %, which includes a 77 wt. % (i.e., 450 mg) lithium carbonate tablet weighing 584 mg; an *optional* pharmaceutically acceptable excipient, which may further comprise a lubricant, such as magnesium stearate, present in an amount

from about 0.5 wt. % to about 1.0 wt. %; a cellulosic binder (i.e., a "dissolution rate stabilizer"), such as microcrystalline cellulose (MC), hydroxypropylmethylcellulose (HPMC), and hydroxyproplycellulose (HPC), present in an amount of about 5 wt. %; fumaric acid (i.e. a "secondary release agent"); and an iron oxide pigment present in trace amounts, such as 0.2 wt. % of a 644 mg tablet, or 1.29 mg iron oxide pigment, which is *about* 1 mg iron oxide pigment per tablet (abstract; column 1, lines 9-22; column 2, lines 4-9, 40-46 and 56-63; column 3, lines 1-7 and 61-67; column 4, lines 1-40 and 59-67; column 5, lines 1-9 and 39-67; column 6, lines 1-6).

Claim Rejections - 35 U.S.C. § 103

The following is a quotation of the appropriate paragraph of 35 U.S.C. § 103, which forms the basis of the obviousness rejections as set forth under this particular section of the Official Action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1. Claims 8 and 62 are rejected under 35 U.S.C. § 103(a) as being unpatentable over the Venkatesh '196 patent in view of U.S. Patent 5,425,950 (hereinafter the Dandiker '950 patent).

The teachings of the Venkatesh '196 patent are incorporated herein by reference and are therefore applied in the instant rejection as discussed hereinabove.

With respect to claims 8 and 62 of the instant application, the Venkatesh '196 patent teaches a controlled release pharmaceutical composition in solid dosage form for oral administration in the treatment of manic depression, wherein said pharmaceutical composition comprises: lithium carbonate present in an amount from about 40 wt. % to about 90 wt. %, which includes a 77 wt. % (i.e., 450 mg)

lithium carbonate tablet weighing 584 mg; an *optional* pharmaceutically acceptable excipient, which may further comprise a lubricant, such as magnesium stearate, present in an amount from about 0.5 wt. % to about 1.0 wt. %; a cellulosic binder (i.e., a "dissolution rate stabilizer"), such as microcrystalline cellulose (MC), hydroxypropylmethylcellulose (HPMC), and hydroxyproplycellulose (HPC), present in an amount of about 5 wt. %; fumaric acid (i.e. a "secondary release agent"); and an iron oxide pigment present in trace amounts, such as 0.2 wt. % of a 644 mg tablet, or 1.29 mg iron oxide pigment, which is *about* 1 mg iron oxide pigment per tablet (abstract; column 1, lines 9-22; column 2, lines 4-9, 40-46 and 56-63; column 3, lines 1-7 and 61-67; column 4, lines 1-40 and 59-67; column 5, lines 1-9 and 39-67; column 6, lines 1-6).

The Venkatesh '196 patent does not explicitly teach utilizing the cellulosic binder sodium carboxymethylcellulose (NaCMC) as the "dissolution rate stabilizer" claimed in claims 8 and 62 of the instant application. However, the Dandiker '950 patent teaches the interchangeability of NaCMC with MC and HPMC, as a disintegrant/binder (column 5, lines 59-62; column 6, lines 15-32). Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the instant application was filed to substitute the NaCMC disintegrant/binder of the Dandiker '950 patent for the cellulosic binders (i.e., "dissolution rate stabilizers") MC and HPMC taught in the Venkatesh '196 patent, as reasonably suggested by the Dandiker '950 patent. One of ordinary skill in the art at the time the instant application was filed would have been motivated to substitute the NaCMC disintegrant/binder of the Dandiker '950 patent for the cellulosic binders (i.e., "dissolution rate stabilizers") MC and HPMC taught in the Venkatesh '196 patent, since the utilization of NaCMC as a disintegrant/binder is conventional in the art of formulating controlled release pharmaceutical compositions, as reasonably suggested by the Dandiker '950 patent.

2. Claims 11-16 and 63 are rejected under 35 U.S.C. § 103(a) as being unpatentable over the Venkatesh '196 patent in view of U.S. Patent 4,346,709 (hereinafter the Schmitt '709 patent).

The teachings of the Venkatesh '196 patent are incorporated herein by reference and are therefore applied in the instant rejection as discussed hereinabove.

With respect to claims 11-16 and 63 of the instant application, the Venkatesh '196 patent teaches a controlled release pharmaceutical composition in solid dosage form for oral administration in the treatment of manic depression, wherein said pharmaceutical composition further comprises fumaric acid (i.e., a "secondary release agent"), present in an amount from about 1 wt. % to about 15 wt. %, preferably from about 3 wt. % to about 15 wt. %, and more preferably from about 6 wt. % to about 13 wt. % (column 2, lines 4-9, 45 and 67; column 3, lines 1-3; column 4, lines 23-24 and 37-39).

The Venkatesh '196 patent does not explicitly teach utilizing glycine as the "secondary release agent" claimed in claims 11-16 and 63 of the instant application. However, the Schmitt '709 patent teaches the interchangeability, as well as the combination, of glycine with fumaric acid, as erosion rate controlling modifiers (i.e., "secondary release agents") for controlling the rate of erosion and thus the rate of release of a drug (column 7, lines 30-40 and 54-56; column 8, lines 2-6 and 43-45). The Schmitt '709 patent also teaches utilizing erosion rate controlling modifiers (i.e., "secondary release agents"), such as glycine and/or fumaric acid, in an amount from about 0.001% to about 40 wt. % (column 8, lines 2-6). Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the instant application was filed to substitute a glycine erosion rate controlling modifier (i.e., "secondary release agent") in an amount from about 0.001% to about 40 wt. %, as taught in the Schmitt '709 patent, for the fumaric acid taught in the Venkatesh '196 patent. One of ordinary skill in the art at the time the instant application was filed would have been motivated to substitute glycine for

fumaric acid, as the utilization of glycine is demonstrated to be a conventional erosion rate controlling modifier (i.e., "secondary release agent") in the art, either alone or in combination with other erosion rate controlling modifiers (i.e., "secondary release agents"), such as fumaric acid, in the formulation of controlled release pharmaceutical compositions, as reasonably suggested by the Schmitt '709 patent.

3. Claims 17 and 18 are rejected under 35 U.S.C. § 103(a) as being unpatentable over the Venkatesh '196 patent in view of the Dandiker '950 patent, and in further view of the Schmitt '709 patent.

The teachings of the Venkatesh '196 patent, the Dandiker '950 patent, and the Schmitt '709 patent are incorporated herein by reference and are therefore applied in the instant rejection as discussed hereinabove.

With respect to claims 17 and 18 of the instant application, the Venkatesh '196 patent teaches a controlled release pharmaceutical composition in solid dosage form for oral administration in the treatment of manic depression, wherein said pharmaceutical composition comprises: lithium carbonate present in an amount from about 40 wt. % to about 90 wt. %; an *optional* pharmaceutically acceptable excipient, which may further comprise a lubricant, such as magnesium stearate; a cellulosic binder (i.e., a "dissolution rate stabilizer"), such as microcrystalline cellulose (MC), hydroxypropylmethylcellulose (HPMC), and hydroxyproplycellulose (HPC), present in an amount from about 5 wt. % to about 30 wt. %; and fumaric acid (i.e., a "secondary release agent) present in an amount from about 1 wt. % to about 15 wt. % (column 1, lines 9-22; column 2, lines 4-9, 40-46, 56-63 and 67; column 3, lines 1-7 and 61-67; column 4, lines 1-40 and 59-67; column 5, lines 1-9 and 39-67; column 6, lines 1-6).

The Venkatesh '196 patent does not explicitly teach utilizing the cellulosic binder sodium carboxymethylcellulose (NaCMC) as the "dissolution rate stabilizer" claimed in claims 17 and 18 of the instant application. However, the Dandiker '950 patent teaches the interchangeability of NaCMC with MC and HPMC, as a disintegrant/binder (column 5, lines 59-62; column 6, lines 15-32). Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the instant application was filed to substitute the NaCMC disintegrant/binder of the Dandiker '950 patent for the cellulosic binders (i.e., "dissolution rate stabilizers") MC and HPMC taught in the Venkatesh '196 patent, as reasonably suggested by the Dandiker '950 patent. One of ordinary skill in the art at the time the instant application was filed would have been motivated to substitute the NaCMC disintegrant/binder of the Dandiker '950 patent for the cellulosic binders (i.e., "dissolution rate stabilizers") MC and HPMC taught in the Venkatesh '196 patent, since the utilization of NaCMC as a disintegrant/binder is conventional in the art of formulating controlled release pharmaceutical compositions, as reasonably suggested by the Dandiker '950 patent.

The Venkatesh '196 patent does not explicitly teach utilizing stearic acid as claimed in claim 17 of the instant application. However, the Dandiker '950 patent teaches the interchangeability of stearic acid, calcium stearate and sodium stearyl fumarate with magnesium stearate (column 5, lines 52-54, column 6, lines 1-2 and 31-32). Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the instant application was filed to substitute magnesium stearate, as taught by the Venkatesh '196 patent, with stearic acid, calcium stearate and sodium stearyl fumarate, as reasonably suggested by the Dandiker '950 patent. One of ordinary skill in the art at the time the instant application was filed would have been motivated to substitute stearic acid, calcium stearate and sodium stearyl fumarate for the magnesium stearate lubricant, as the utilization of stearic acid, calcium

stearate and sodium stearyl fumarate as a lubricant are conventional in the art of formulating controlled release pharmaceutical compositions, as reasonably suggested by the Dandiker '950 patent.

The Venkatesh '196 patent does not explicitly teach utilizing glycine as the "secondary release agent" claimed in claims 17 and 18 of the instant application. However, the Schmitt '709 patent teaches the interchangeability, as well as the combination, of glycine with fumaric acid, as erosion rate controlling modifiers (i.e., "secondary release agents") for controlling the rate of erosion and thus the rate of release of a drug (column 7, lines 30-40 and 54-56; column 8, lines 2-6 and 43-45). The Schmitt '709 patent also teaches utilizing erosion rate controlling modifiers (i.e., "secondary release agents"), such as glycine and/or fumaric acid, in an amount from about 0.001% to about 40 wt. % (column 8, lines 2-6). Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the instant application was filed to substitute a glycine erosion rate controlling modifier (i.e., "secondary release agent") in an amount from about 0.001% to about 40 wt. %, as taught in the Schmitt '709 patent, for the fumaric acid taught in the Venkatesh '196 patent. One of ordinary skill in the art at the time the instant application was filed would have been motivated to substitute glycine for fumaric acid, as the utilization of glycine is demonstrated to be a conventional erosion rate controlling modifier (i.e., "secondary release agent") in the art, either alone or in combination with other erosion rate controlling modifiers (i.e., "secondary release agents"), such as fumaric acid, in the formulation of controlled release pharmaceutical compositions, as reasonably suggested by the Schmitt '709 patent.

4. Claims 6 and 7 are rejected under 35 U.S.C. § 103(a) as being unpatentable over the Venkatesh '196 patent in view of U.S. Pre-Grant Patent Application Publication 2002/0056206 (hereinafter the Pace '206 publication).

The teachings of the Venkatesh '196 patent are incorporated herein by reference and are therefore applied in the instant rejection as discussed hereinabove.

With respect to claims 6 and 7 of the instant application, the Venkatesh '196 patent teaches a controlled release pharmaceutical composition in solid dosage form for oral administration in the treatment of manic depression, wherein said pharmaceutical composition is compressed into tablets (column 2, lines 10-12; column 3, lines 53 and 60).

The Venkatesh '196 patent does not explicitly teach a specific pressure utilized when compressing said pharmaceutical composition into tablets, as claimed in claims 6 and 7 of the instant application. However, the Pace '206 publication teaches compressing a pharmaceutical composition comprising a therapeutic agent, excipients and magnesium stearate into a solid tablet dosage form for oral administration, wherein said pharmaceutical composition is compressed at a hardness and pressure from about 2 kPa to about 9 kPa ([0285]). Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the instant application was filed to compress a pharmaceutical composition comprising a therapeutic agent, excipients and magnesium stearate into a solid tablet dosage form for oral administration, as taught by the Venkatesh '196 patent, at a hardness and pressure from about 2 kPa to about 9 kPa, as reasonably suggested by the Pace '206 publication. One of ordinary skill in the art at the time the instant application was filed would have been motivated to compress a pharmaceutical composition comprising a therapeutic agent, excipients and magnesium stearate at a hardness and pressure from about 2 kPa to about 9 kPa, so as to obtain a solid tablet dosage form for oral administration, as reasonably suggested by the Pace '206 publication.

Conclusion

Claims 1-8, 11-18 and 61-63 stand rejected because the claimed invention would have been anticipated and/or prima facie obvious to one of ordinary skill in the art at the time the instant application was filed since each and every element of the claimed invention, as a whole, is disclosed in and would have been reasonably suggested by the teachings of the cited prior art references.

Examiner's Response to Applicants' Remarks

Although Applicants' arguments, as set forth in the aforementioned Response, have been fully considered in light of the claims as currently amended, Applicants' arguments are deemed unpersuasive.

The rejections set forth in the aforementioned Official Action rejecting claims 9, 10 and 19-60 as being anticipated and/or prima facie obvious to one of ordinary skill in the art at the time the instant application was filed by the disclosure and/or teachings of the cited prior art references, are moot in light of the cancellation of said claims.

1. The rejection of claims 1-5 under 35 U.S.C. § 102(b) as being anticipated by the Venkatesh '196 patent.

Applicants argue on page 5 of the aforementioned Response that the Venkatesh '196 patent does not disclose a composition and/or dosage form employing a dissolution rate stabilizer in the amounts recited in the claims as currently amended. In response to Applicants' arguments, the Venkatesh '196 patent discloses a cellulosic binder, such as microcrystalline cellulose (MC), hydroxypropylmethylcellulose (HPMC), and hydroxyproplycellulose (HPC), present in an amount from about 5 wt. % to about 30 wt. %, which anticipates a "dissolution rate stabilizer" as broadly

claimed (abstract; column 1, lines 9-12; column 2, lines 61-63; column 3, lines 3-7 and 61-64; column 4, lines 6-10 and 33-36).

2. The rejection of claim 8 under 35 U.S.C. § 103(a) as being unpatentable over the Venkatesh '196 patent in view of the Dandiker '950 patent.

Applicants argue on pages 5 of the aforementioned Response that the Venkatesh '196 patent does not teach a composition employing a dissolution rate stabilizer in the amounts recited in the claims as currently amended. In response to Applicants' arguments, a proper prima facie case of obviousness with respect to the 35 U.S.C. § 103(a) rejection of claim 8 as being unpatentable over the Venkatesh '196 patent in view of the Dandiker '950 patent is set forth hereinabove.

Applicants argue on page 6 of the aforementioned Response that the Dandiker '950 patent merely teaches that NaCMC can be used in a pharmaceutical composition as an excipient, such as a disintegrant. In response to Applicants' arguments, merely substituting interchangeable elements, which are conventionally utilized for the same art-recognized purpose, followed by identifying said substituted interchangeable element with a label that differs from the label identifier utilized in the prior art to characterize said substituted interchangeable element, does not rise to the level of patentability. In essence, the instant claims are drawn to an interchangeable element that is an obvious variation over the prior art, followed by a lexicographic modification of a label identifier utilized to characterize said interchangeable element. More specifically, the instantly claimed composition comprises NaCMC. Although the Venkatesh '196 patent teaches a pharmaceutical composition comprising MC, HPMC, and/or HPC, the Venkatesh '196 patent does not explicitly teach a pharmaceutical composition comprising NaCMC. However, the Dandiker '950 patent teaches the

interchangeability of NaCMC with MC and HPMC. Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the instant application was filed to substitute the NaCMC taught by the Dandiker '950 patent, for the MC and HPMC taught in the Venkatesh '196 patent. The fact that the Venkatesh '196 patent and the Dandiker '950 patent characterize NaCMC with a label identifier (i.e., disintegrant/binder) that is different from the instantly claimed label identifier (i.e., dissolution rate stabilizer) for characterizing NaCMC is immaterial, as NaCMC is NaCMC regardless of how a lexicographer decides to identify or characterize NaCMC.

Applicants argue on page 6 of the aforementioned Response that the Dandiker '950 patent teaches utilizing NaCMC in an amount that far exceeds the amounts of NaCMC as instantly claimed. In response to Applicants' arguments, the Dandiker '950 patent is simply relied upon for the teaching of the interchangeability of NaCMC with MC and HPMC, while the Venkatesh '196 patent provides a teaching of the relative amounts of said cellulosic derivatives.

Applicants argue on page 6 of the aforementioned Response that the Dandiker '950 patent fails to teach a pharmaceutical composition comprising lithium carbonate and that one of ordinary skill in the art would not turn to the teachings of the Dandiker '950 patent when considering employing a dissolution rate stabilizer such as NaCMC. In response to Applicants' arguments, the Dandiker '950 patent is not being relied upon for a teaching of incorporating lithium carbonate into a controlled release pharmaceutical composition, since such a teaching is provided by the teachings of the Venkatesh '196 patent. In addition, one of ordinary skill in the art would in fact turn to the teachings of the Dandiker '950 patent, which is entitled "Controlled Release Pharmaceutical Compositions," when considering employing NaCMC as a disintegrant for the controlled release of a pharmaceutical compound.

3. The rejection of claims 11-16 under 35 U.S.C. § 103(a) as being unpatentable over the Venkatesh '196 patent in view of the Schmitt '709 patent;

4. The rejection of claims 17 and 18 under 35 U.S.C. § 103(a) as being unpatentable over the Venkatesh '196 patent in view of the Dandiker '950 patent, and in further view of the Schmitt '709 patent; and

5. The rejection of claims 6 and 7 under 35 U.S.C. § 103(a) as being unpatentable over the Venkatesh '196 patent in view of the Pace '206 publication.

Applicants' arguments with respect to the rejection of: claims 11-16 under 35 U.S.C. § 103(a) as being unpatentable over the Venkatesh '196 patent in view of the Schmitt '709 patent; claims 17 and 18 under 35 U.S.C. § 103(a) as being unpatentable over the Venkatesh '196 patent in view of the Dandiker '950 patent, and in further view of the Schmitt '709 patent; and claims 6 and 7 under 35 U.S.C. § 103(a) as being unpatentable over the Venkatesh '196 patent in view of the Pace '206 publication, do not comply with 37 CFR § 1.111(c) because the arguments set forth in the aforementioned Response do not clearly point out the patentable novelty and unobviousness associated with the instant claims in view of the rejections made over the state of the art as disclosed and taught by the cited prior art references.

Claims 1-8, 11-18 and 61-63 stand rejected because the claimed invention would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made since each and every element of the claimed invention, as a whole, would have been reasonably suggested by the teachings of the cited prior art references.

Conclusion

Applicants' claim amendments necessitated the new grounds of rejection presented in this Official Action. Accordingly, **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR § 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR § 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to David P. Stitzel, M.S., Esq., whose telephone number is 571-272-8508. The Examiner can normally be reached on Monday-Friday, from 7:30AM-6:00PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Mr. Johann Richter, Ph.D., Esq., can be reached at 571-272-0646. The central fax number for the USPTO is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published patent applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished patent applications is only available through Private PAIR. For more information about the PAIR system, please see http://pair-direct.uspto.gov. Should you have questions about acquiring access to the Private PAIR system, please contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David P. Stitzel, M.S., Esq.
Patent Examiner
Technology Center 1600
Group Art Unit 1616
May 2, 2006

Johann Richter, Ph.D., Esq.
Supervisory Patent Examiner
Technology Center 1600
Group Art Unit 1616